REMARKS

Claims 1-8 are pending. Claims 6-8 were objected to, claims 1 and 4-8 were rejected under the judicially created doctrine of obviousness-type double patenting, and claims 6-8 were rejected under 35 U.S.C. § 112, first paragraph.

Amendments to the Specification

Applicants amend the Brief Description of the Drawings to include sequence identifiers for the sequences shown in the figures and amend the description of Figure 6 to correct a typographical error. Applicants also amend the paragraph beginning at page 8, line 28, to correct a typographical error. This amendment finds support, for example, at page 13, lines 12-14, of the specification, and in Figure 11. No new matter has been added by the amendments.

Claims amendments

Claim 6 has been amended to be directed to an isolated cell that includes the vector of claim 5. Support for this amendment may be found, for example, at page 24, line 28, to page 25, line 7, of the specification. Claims 7 and 8 have been amended to reflect the amendment to claim 6. In addition, Applicants add new claim 9. Support for this claim may be found, for example, at 22, line 3, to page 23, line 28, of the specification. No new matter has been added by these amendments.

Objections to the claims and the specification

Applicants have amended the specification to include sequence identifiers in the Brief Description of the Drawings for all sequences shown in the figures and correct the typographical error at page 8, line 32. The objection to the specification should be withdrawn.

Claims 6-8 have been amended to be directed to an isolated cell including the vector of claim 5. Applicants submit that this amendment overcomes the Office's objection to these claims.

Rejection under the judicially created doctrine of obviousness-type double patenting

Claims 1 and 4-8 were rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 6-10 of U.S. Patent No. 6,312,947. Applicants agree to submit a Terminal Disclaimer to overcome this rejection upon indication that the claims otherwise are in condition for allowance.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 6-8 were rejected under 35 U.S.C. § 112, first paragraph, for a lack of enablement. In particular, the Office asserts (page 5):

> The claims encompass vectors inside cells *in vivo*. The vector within a cell, such as a plant cell or a mammalian cell, in a subject must have a use, thus, the claims read on gene therapy *in vivo*.

The Office also cites a number of references (Deonarian, Exp. Opin. Ther. Patents 8:53-69, 1998; Verma and Somia, Nature 389:239-242, 1997; Eck and Wilson, Goodman & Gilman's The Pharmacological Basis of Therapeutics, Ninth Edition, McGraw-Hill, NY, pp. 77-101, 1996; and Górecki, Expert Opin. Emerging Drugs 6:187-198, 2001) to support the assertion that *in vivo* gene therapy is unpredictable and not enabled by Applicants' specification.

Claims 6-8 have been amended to be directed to an isolated cell that includes the vector of claim 5. With regard to the standard for enablement, Applicants note that the Federal Circuit has long held that it is not necessary for all possible embodiments of a claim to be operative in order for that claim to be enabled. *See Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569 (Fed. Cir. 1984). The proper test of enablement is "whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with the information known in the art without undue experimentation." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d. 1318 (Fed. Cir. 1985). Applicants' specification, as filed, clearly meets this standard for claims 6-8.

As a preliminary matter, Applicants note that claims 6-8 clearly do not require a cell to be in a subject. Applicants' specification describes the use of isolated cells, for example, at page 24, line 28, to page 25, line 18, in screening for compounds that increase or decrease the activity of cell protective genes. Further, the specification teaches that the

claimed isolated cells may be produced by a number of standard methods as described, for example, at page 24, lines 31-34, and page 47, lines 10-14. Moreover, as is taught at page 27, line 27, to page 28, line 31, of the specification, compounds that increase cell death have a wide variety of uses, including as anti-viral and anti-parasitic agents. Clearly, the specification enables one skilled in the art to make and use the presently claimed cells. None of the cited references casts any doubt on the feasibility of using isolated cells containing a vector to screen for compounds that affect gene activity.

As is noted above, the standard for enablement is not that all possible embodiments of a claim need to be enabled, but rather that one skilled in the art could make and use the invention without undue experimentation. In view of Applicants' teachings, one skilled in the art clearly would know how to make and use the claimed cells for a variety of purposes, including screening for compounds that alter the activity of cell protective genes, without undue experimentation. The 35 U.S.C. § 112, first paragraph, rejection of claims 6-8 should be withdrawn.

Applicants also submit that new claim 9 also is enabled by their specification. Claim 9 is directed to a nematode cell comprising the vector of claim 5. The specification, for example, at page 23, line 7, to page 24, line 17, page 44, line 22, to page 45, line 3, and page 46, line 20, to page 47, line 8, teaches how to make and use both an isolated cell and a transgenic nematode expressing a claimed vector. For instance, with regard to the use of such cells, the specification teaches (page 24):

[T]ransgenic animals in which ced-9 is underexpressed or

> inactivated could be used to identify agents that mimic ced-9 in preventing cell death or which act as agonists of cell death-protective activity. Likewise, ... transgenic animals in which ced-9 is overexpressed or constitutively activated can be used to identify agents which act as antagonists of cell death-protective activity.

For all the above reasons, Applicants submit that claim 9 is enabled by their specification and is in condition for allowance.

CONCLUSION

As is stated above, Applicants agree to submit a Terminal Disclaimer when the Office determines that the claims otherwise are in condition for allowance. Thus, once this determination has been made, to expedite prosecution, Applicants respectfully request that the Examiner telephone the undersigned attorney regarding this matter and Applicants will promptly submit the Terminal Disclaimer.

Enclosed is a Petition to extend the period for replying to the Office Action for three months, to and including September 12, 2003, and a check in the amount of $930.00 in payment of the required extension fee. If there are any additional charges or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

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